K121684

Exactech® Novation® LPI Prime Femoral Stem
Traditional 510(k)

510(k) Summary

OCT 1 2012

Company: Exactech®, Inc
2320 NW 66th Court
Gainesville FL, 32653

Date: September 24, 2012

Contact Person: Vladislava Zaitseva
Regulatory Affairs Specialist II
Telephone: (352) 327-4674
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Proprietary Name: Exactech® Novation® LPI Prime Femoral Stem

Common Name: Femoral Hip Stem

Classification Name:

Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented Or Non-Porous, Uncemented (21 CFR Section 888.3353, Class II, Product Code LZO)

Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented Or Uncemented (21 CFR Section 888.3390, Class II, Product Code KWY)

Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Porous Uncemented (21 CFR 888.3358, Device Class: II, Product Code: LPH)

Legally Marketed Device to Which Substantial Equivalence Is Claimed:

Name	Manufacturer	510(k) Number
Metha Short Stem Hip System	Aesculap	K080584 and K112682

Device Description

The Novation LPI Prime Femoral Stem is a titanium press-fit prosthesis featuring a 12/14 trunnion that is used on the femur side of a total or hemi hip arthroplasty. The proximal region of the stem is coated with porous titanium plasma spray for uncemented, biological fixation.

The proposed femoral stems are intended to mate with the following modular 12/14 femoral heads:

- Exactech Cobalt Chromium Alloy Femoral Heads (K041906)
- Exactech Ziramic Zirconia Femoral Heads (K050398, K060107)
- Exactech BIOLOX®forte Alumina Femoral Heads (K032964, K051682)
- Exactech *Biolox*Delta and *Delta*Option Femoral Heads and Adapters (K103012)
- AcuMatch L-series Unipolar endoprosthesis (K010081)

The proposed femoral stems are intended to mate with the following bipolar components:

- AcuMatch L-Series Bipolar Endoprosthesis (K013211)

Indications for Use

All Exactech Hip Systems are indicated for use in skeletally mature individuals undergoing primary surgery for hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, post-traumatic degenerative problems of the hip, and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment. Components of Exactech Hip Systems are also potentially indicated for ankylosing spondylitis, congenital hip dysplasia, revision of failed previous reconstructions where sufficient bone stock is present, and to restore mobility resulting from previous fusion.

- Cemented femoral stems and cemented acetabular cups are intended for cemented fixation only.
- Press-fit femoral stems and acetabular cups are intended for press-fit fixation.
- Femoral heads and endoprostheses are intended for use in cemented and press-fit applications.

Summary of Technological Characteristics

The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use.** The proposed Novation LPI Prime Femoral Stems and predicate devices have similar indications for use.
- **Materials.** The proposed Novation LPI Prime Femoral Stems and predicate devices are composed of materials conforming to recognized industry standards for permanent implants.
- **Sterilization processes.** The proposed Novation LPI Prime Femoral Stems and predicate devices are provided sterile for single use and conform to recognized industry standards.
- **Design Features.** The proposed Novation LPI Prime Femoral Stems and predicate devices incorporate similar design features.
- **Performance specifications.** The proposed Novation LPI Prime Femoral Stems and predicate devices conform to recognized performance standards for total hip replacement devices.

Substantial Equivalence Conclusion

Results from mechanical testing, engineering analyses, simulated surgical implantations and literature reviews demonstrate the proposed Novation LPI Prime Femoral Stems are substantially equivalent to the predicate devices. A summary of these tests and analyses are as follows:

- Clinical Literature Review of similar femoral prostheses
- Cadaver lab validation demonstrating the design features (including outside geometry and overall scope).
- Finite Element Analyses for determination of worst case size for testing.

- Range of Motion testing per EN ISO 21535, Non-active surgical implants -- Joint replacement implants -- Specific requirements for hip-joint replacement implants
- Distally Fixed FatigueWorst case Press-fit Fatigue Testing per FDA guidance
- Femoral Neck FatigueWorst case Press-fit Fatigue Testing per FDA guidance
- Femoral Head Modular Junction Burst Testing and Axial pull-off Testing on the taper specification

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Exactech, Incorporated
% Ms. Vladislava Zaitseva
Regulatory Affairs Specialist II
2320 NW 66th Court
Gainesville, Florida 32653

OCT 1 2012

Re: K121684
Trade/Device Name: Exactech® Novation® LPI Prime Femoral Stem
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, LZO, KWY
Dated: September 11, 2012
Received: September 12, 2012

Dear Ms. Zaitseva:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number: K121684

Device Name: Exactech® Novation® LPI Prime Femoral Stem

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Prescription Use X **and/or** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

Please do not write below this line - use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121684